

REMARKS

Entry of this amendment and favorable reconsideration of this application is requested.

Claims 1-51 are in the case.

Claims 24-31 stand withdrawn from further consideration as not reading on the elected invention. As so noted by the Examiner, rejoinder of these claims will be considered by him upon the allowance of the product claims if these process claims are made to depend on the product claims. Such has now been done. It is thus requested that rejoinder of nonelected process Claims 24-31 be effected upon allowance of the other claims.

Claims 1-23, 32 and 34-51 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Masaki et al.

Claim 33 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Masaki et al. in view of Tsuchiya et al.

The interview kindly granted by the Examiner, Mr. Guarriello, on February 11, 2004, and subsequent telephonic discussion with him are herewith greatly appreciated. They served to materially advance the prosecution of the case by clarifying the issues. Specifically, for reasons as pointed out to him at said interview as set forth and further elaborated below, and in view of the amendment to the claims made herewith, the Examiner stated that he will reconsider his position.

It is submitted that the above set forth rejections under 35 U.S.C. § 102 and § 103 are improper, they again being traversed.

Specifically, the present invention relates to a water-absorbing composite, comprising water-absorbing polymer particles immobilized on a fibrous substrate wherein at least a part of said water-absorbing polymer particles comprise primary particles having an average particle diameter of about 50-1000 μm , wherein about 30% by weight or more of said

primary particles are combined to form agglomerates having a shape satisfying the following conditions while nearly maintaining their primary particle shapes and a part of particles of said agglomerates are not adhered to said fibrous substrate:

Average particle diameter (D) $100 \leq D \leq 3000 \mu\text{m}$

Average relative displacement of the direction by direction analysis (θ) $10 \leq \theta \leq 25$

Frequency analysis 5 Hz/20 Hz intensity ratio (k) $0.6 \leq k \leq 0.9$

Agglomerate maximum length (L)/minimum length (l) ratio $1.2 \leq L/l \leq 15.0$,

as well as to a process for its preparation.

Such water-absorbing composite containing agglomerates of water-absorbing polymer particles stably immobilized on a fibrous substrate have good water-absorbing properties, a high water-absorbing speed and excellent immobility of gel after absorbing water. Note the examples and comparative examples in the case.

Masaki et al. clearly neither teaches, nor, in fact, makes obvious Applicants' discovery, within the meaning of 35 U.S.C. § 102 or § 103. To the contrary, the reference actually teaches away from the claimed invention. As so summarized by Masaki et al. in its Abstract:

The absorbent sheet comprising at least hydrophilic fibers and thermally fusible bonding fibers or a strengthening assistant, and a superabsorbent polymer is characterized in that the superabsorbent polymer is not present on an absorbent surface of the absorbent sheet for absorbing liquid but distributed inside the absorbent sheet, and is adhered and fixed to the hydrophilic fibers constituting the absorbent sheet, the superabsorbent polymer is spread at an amount of 5 to 300 g per 1 m^2 of the absorbent sheet and the absorbent sheet has thickness of 0.3 to 1.5 mm.

In the present invention, on the other hand, as so specifically recited in the claims, the water-absorbing polymer particles are immobilized on either only one side or both sides of a fibrous substrate in the form of agglomerates having the defined shape. Contrariwise, as so disclosed by Masaki et al., its super absorbent polymer is embedded in spaces formed among

fibers constituting the absorbent sheet. Specifically, as so considered essential by patentees, as note, col. 3, lines 29-33 and 63-67:

the super absorbent polymer is not present on an absorbent surface of the absorbent sheet for absorbing liquid but distributed inside the absorbent sheet, and is adhered and fixed to the hydrophilic fibers constituting the absorbent sheet;

the super absorbent polymer is not present on an absorbent surface of the absorbent sheet for absorbing liquid but distributed inside the absorbent sheet, and is adhered and fixed to the hydrophilic fibers constituting the absorbent sheet;

Thus, even if arguendo, the superabsobent polymer particles agglomerate, as so disclosed at column 5, lines 6-11 of Masaki et al., encompass the claimed agglomerate, nevertheless, they are neither present on a fibrous substrate, nor have a specific shape as particularly called for by the claims, the Examiner's assertion of "inherency" with regard to such shape thus also being misplaced. Note Ex parte Levy, 17 USPQ 2d 1461, a rejection for "inherency" requiring such to be a necessary and inevitable result. Clearly, it thus cannot reasonably be said that anticipation, within the meaning of 35 U.S.C. § 102 requiring complete identity in the art, is present. In fact, basically and completely different structures are involved.

In fact, even considering the rejection as having been made under 35 U.S.C. § 103, Applicants' discovery is not obvious. Note the examples and comparative examples in the case which clearly demonstrate unobvious results for the claimed limitations obviating even any presumption of a *prima facia* case. Specifically, note the Tables setting forth the results of the examples according to the invention and comparative examples, as well as to the discussion and interpretation of their results set forth at pages 36-37 of the specification. The unobviously superior results so shown thus also rebut any possible *prima facie* case of

obviousness conceivably made out by the art, even if the rejection is considered to have been made under 35 U.S.C. § 103.

Further, while a showing of unobviously superior results is not relevant to a rejection under 35 U.S.C. § 102, nevertheless, superiority for the claimed invention also has been shown by direct comparative evidence with the closest prior art, i.e. Masaki et al., as note the Sugyo Declaration under 37 C.F.R. § 1.112 submitted with the response of July 24, 2003. The nature of the superabsorbent polymer compared with, although its preparation is not disclosed in the Declaration, inasmuch as it is a commercially available product, clearly is set forth in the showing and the advantageous and superior results as set forth in said Declaration also clearly rebut any possible *prima facie* case of obviousness conceivably made out by Masaki et al.

With regard to the rejection of Claim 33 under 35 U.S.C. § 103 over Masaki et al. in view of Tsuchiya et al., Tsuchiya et al. is relied upon only for obviousness of process limitations in the preparation of the water-absorbing composite. Such process limitations for the preparation of the article of Masaki et al., however, manifestly contradict the objective of this reference, Tsuchiya et al. thus clearly not being properly combined with nor remedying the inadequacies of the primary reference.

Accordingly, withdrawal of the rejection to claims under 35 U.S.C. § 102 and § 103 is requested.

With regard to the Examiner's objection under 35 U.S.C. § 1.132 with regard to the amendment to page 30, lines 14 to 17 of the specification as assertedly is not being supported by the disclosure is traversed. The Sugyo Declaration under 37 C.F.R. § 1.132 also filed July 24, 2003, clearly establishes, as so attested to by Declarant, that by further measurements of the agglomerates actually prepared, all of them of are orthogonal. Such ascertainment of a fact actually being present manifestly is not "new matter". It only confirms the nature of the

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Reply to Office Action of November 10, 2003

product actually prepared, explicitly disclosing that which is implicitly disclosed. Note In re Wright, 145 USPQ 182; In re Nathan, 140 USPQ 601 and In re Magerlein et al, 145 USPQ 683.

It is submitted that this application is now in condition for allowance and which is solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.


Masayasu Mori
Attorney of Record
Registration No. 47,301

Samuel H. Blech
Registration No. 32,082

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220

NFO/SHB:law

**FULL TEXT OF CASES (USPQ2D)**
All Other Cases**Ex parte Levy (BdPatApp&Int) 17 USPQ2d 1461 Ex parte Levy****U.S. Patent and Trademark Office, Board of Patent Appeals and
Interferences
17 USPQ2d 1461**

**Decided October 16, 1990
No. 90-1864**

Headnotes**PATENTS****1. Patentability/Validity - Anticipation - Identity of elements (§ 115.0704)**

Factual determination of anticipation requires disclosure in single reference of every element of claimed invention, and examiner must identify wherein each and every facet of claimed invention is disclosed in applied reference.

2. Patentability/Validity - In general (§ 115.01)**Patentability/Validity - Anticipation - Prior art (§ 115.0703)**

Initial burden of establishing prima facie basis to deny patentability rests upon examiner; examiner, if relying upon theory of inherency, must provide basis in fact and/or technical reasoning to reasonably support determination that allegedly inherent characteristic necessarily flows from teachings of applied prior art.

3. Patentability/Validity - Anticipation - Prior art (§ 115.0703)

Examiner erred by rejecting claims for biaxially oriented catheter balloon as anticipated by prior art which does not disclose such biaxially oriented balloon and which has not been shown to be inherently biaxially oriented.

4. Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (§ 115.0903.03)

Examiner erred by rejecting claims for biaxially oriented balloon catheter under 35 USC 103 based upon combined disclosure of two prior art references, one of which was relied upon solely for disclosed use of high viscosity polyethylene terephthalate tubing and the other which was presupposed by examiner to disclose biaxially oriented catheter balloon, since examiner has not established that resulting catheter balloon using high viscosity tubing is biaxially oriented.

Case History and Disposition:

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Application of Stanley B. Levy, serial no. 287,234, filed Dec. 21, 1988, which is a division of serial no. 914,108, filed Oct. 1, 1986, now Re. 32,983, granted July 4, 1989; and a reissue of serial no. 510,812, filed July 5, 1983, now patent no. 4,490,421, granted Dec. 25, 1984, for balloon and manufacture thereof. From examiner's rejection of claims 13 through 17 and 25 (James Seidleck, primary)

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examiner), applicant appeals. Reversed.

Attorneys:

Louis H. Rombach, Wilmington, Del., for appellant.

Judge:

Before Steiner, Tarring, and J. Smith, examiners-in-chief.

Opinion Text

Opinion By:

Steiner, examiner-in-chief.

This is an appeal from the final rejection of claims 13 through 17 and 25, which are all of the claims remaining in this application for reissue of U.S. Patent No. 4,490,421.

The subject matter on appeal is directed to a polymeric balloon exhibiting properties which enable its use as a

catheter balloon for medical dilation procedures, such as coronary angioplasty wherein a catheter with a balloon at a distal end thereof is inserted into coronary arteries and inflated. The balloon must be capable of exerting sufficient pressure to dilate stenotic lesions without rupture of the balloon.

Claims 13 and 25, the only independent claims on appeal, read as follows:

13. *High molecular weight, biaxially oriented, flexible polymeric balloon having a wall tensile strength of at least 31,714 psi (218.86 MPa).*

25. *High molecular weight, biaxially oriented, flexible polyethylene terephthalate dilatation catheter balloon.*

The references relied upon by the examiner are:

Wyeth et al. (Wyeth)	3,733,309	May 15, 1973
Schjeldahl et al. (Schjeldahl '989)	4,413,989	Nov. 8, 1983 1
Schjeldahl et al. (Schjeldahl '000)	4,456,000	June 26, 1984 2

Claims 13, 14, 16, 17 and 25 stand rejected under 35 U.S.C. 102 as anticipated by Schjeldahl. Claims 13 through 17 stand rejected under 35 U.S.C. 103 based upon "Schjeldahl et al in view of Wyeth as set forth in the Final Rejection" (paragraph bridging pages 3 and 4 of the Answer). We reverse each rejection.

The Rejection of Claims 13, 14, 16, 17 and 25 Under 35 U.S.C. §102.

[1] The factual determination of anticipation requires the disclosure in a single reference of every element of the claimed invention. *In re Spada*, — F.2d —, 15 USPQ2d 1655 (Fed. Cir. 1990); *In re Bond*, — F.2d —, 15 USPQ2d 1566 (Fed. Cir. 1990); *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 7 USPQ2d 1057 (Fed. Cir. 1988); *Alco Standard Corp. v. TVA*, 808 F.2d 1490, 1 USPQ2d 1337 (Fed. Cir. 1986); *In re Marshall*, 578 F.2d 301, 198 USPQ 344 (CCPA 1978); *In re Arkley*, 455 F.2d 586, 172 USPQ 524 (CCPA 1972). Moreover, it is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984).

Each of the independent claims on appeal defines a polymeric balloon which is "biaxially oriented." Ergo, in order to establish a *prima facie* basis to defeat the patentability of independent claims 13 and 25 under 35 U.S.C. §102, the examiner is obliged to point out where Schjeldahl discloses a *biaxially oriented* polymeric balloon. The tenor of the final rejection and Answer presupposes that Schjeldahl discloses a biaxially oriented polymeric balloon.

See, for example, page 5 of the Final Rejection wherein the examiner states

he reference clearly teaches a biaxially oriented balloon catheter, and states that it is made by injection blow molding.

See, also, page 5 of the Answer wherein the examiner states

rguments that the references don't disclose a biaxially oriented PET (polyethylene terephthalate) balloon catheter is contrary to what is *clearly stated* in the references (emphasis supplied).

The examiner does not point to, and we do not find, any express disclosure in Schjeldahl of a biaxially oriented polymeric balloon.

It would appear that the relevant evulgations in Schjeldahl which may have led the examiner to his determination are:

(a) an expander 3 formed *from* a thin, flexible inelastic, high tensile strength, *biaxially oriented* synthetic plastic material

(column 2 of Schjeldahl '989, lines 63 through 65, emphasis supplied);
(b) The expander 30 is preferably formed *from* a suitable synthetic plastic material, such as *biaxially oriented polypropylene*, *by an injection blow molding operation* and, as such, is substantially inelastic in both the axial and radial directions and may, for example, have a finished wall thickness in the range of from 0.005 to 0.200 millimeters, 0.025 millimeters being typical (column 6 of Schjeldahl '989, lines 45 through 52, emphasis supplied);
(c) It has been found that an expander of the above-dimensional characteristics can withstand internal inflation pressure in excess of 7 atmospheres without fear of rupture (column 6 of Schjeldahl '989, lines 62 through 65);
(d) injection blow molding step used to form the expander 30 (column 8, lines 16 and 17);
(e) the expander 30 is formed *from* a thin plastic material capable of withstanding relatively high internal pressures without rupture and without exceeding the elastic limit for the material itself (column 10 of Schjeldahl '989, lines 32 through 36, emphasis supplied);
(f) the expander 82 is preferably formed *from* a suitable synthetic plastic material such as *biaxially oriented polypropylene* or *biaxially oriented polyethylene terephthalate by an injection molding operation* and, as such, is substantially inelastic in both the axial and radial direction (column 12 of Schjeldahl '989, lines 22 through 37, emphasis supplied); and
(g) Apparatus as in claim 1 wherein said non-elastic expander member comprises a longitudinally extending thin, flexible, tubular element *formed from a biaxially oriented* synthetic plastic material surrounding said outer tubular member with opposed ends thereof secured to said outer tubular member at spaced apart locations proximate said distal end thereof (claim 8 of Schjeldahl '989, emphasis supplied).

These excerpts do not justify the determination that Schjeldahl discloses a biaxially oriented polymeric balloon. According to Schjeldahl, the *starting* material is a biaxially oriented synthetic plastic material, such as polyethylene terephthalate. The *final article*, i.e., the expander or catheter balloon, is *not characterized as biaxially oriented*. Moreover, it would appear to be *undisputed* that the *only* method disclosed by Schjeldahl for transforming the biaxially oriented *starting* plastic into the *final* catheter balloon, i.e., injection blow molding, is *not* capable of producing a biaxially oriented catheter balloon. In fact, it is *undisputed* that injection blow molding would *destroy* the biaxial orientation of the plastic starting material. We refer to the Belcher affidavits, Exhibits V, VI and VIII, 4 which factually set forth the differences between "injection blow molding" and "injection stretch blow molding," and support the conclusion that the "injection blow molding" process disclosed by Schjeldahl could not possibly produce a biaxially oriented polymeric balloon. 5

Indeed, the examiner agrees with appellant's position that injection blow molding could *not* produce a biaxially oriented balloon. See, for example, page 5 of the Final Rejection wherein the examiner states:
statements that injection blow molding without stretching will not produce a biaxially oriented article are *true* ... (emphasis supplied).

The examiner goes on, in the same sentence, to state:

but since the reference produces a biaxially oriented article, clearly a stretching step must be used.

Again, on page 5 of the Answer, the examiner states:

Since Schjeldahl et al produces a biaxially oriented article it follows that a stretching step must be used in the injection blow molding process.

The inescapable facts are that Schjeldahl does not disclose a biaxially oriented catheter balloon and does not mention a stretching step.

[2] The examiner also relies upon the theory that Schjeldahl's catheter balloon is inherently biaxially oriented. On page 4 of the Answer, the examiner points out that inasmuch as the Patent and Trademark Office does not have the requisite laboratory equipment for testing, the burden shifts to appellant. However, the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests

upon the examiner. *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984). In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); *In re Oelrich*, 666 F.2d 578, 212 USPQ 323 (CCPA 1981); *In re Wilding*, 535 F.2d 631, 190 USPQ 59 (CCPA 1976); *Hansgirg v. Kemmer*, 102 F.2d 212, 40 USPQ 665 (CCPA 1939). In our opinion, the examiner has not discharged that initial burden.

Schjeldahl does not provide any working example revealing the process conditions employed to produce the catheter balloon. We have *only* a general invitation to employ "injection blow molding." As previously discussed, it is undisputed that injection blow molding would *not* have produced a biaxially oriented balloon and would have destroyed the biaxially orientation of a polymeric starting material.

Schjeldahl does not disclose any particular tensile strength of the catheter balloon. We do not find sufficient factual basis or cogent scientific reasoning to support the conclusion that Schjeldahl's disclosure with respect to the ability of the catheter balloon to "withstand an internal inflation pressure in excess of 7 atmospheres without fear of rupture" (column 6 of Schjeldahl '989, lines 63 through 65) *necessarily* means that the catheter balloon is biaxially oriented. According to the membrane equation calculations reported in Levy's declaration (Exhibit IV), Schjeldahl's balloon could not possibly exhibit the tensile characteristics of a biaxially oriented balloon. Levy's calculations are *inconsistent* with those of Pinchuk (Exhibit III). Suffice it to say, the conflicting calculations taint the factual determination of inherency with impermissible conjecture. Indeed, the examiner, in the paragraph bridging pages 4 and 5 of the Answer, states that

the membrane equation used to determine the tensil [sic, tensile] strength can be manipulated to produce any desired value, and thus is misleading.

Nevertheless, the examiner goes on to favor Pinchuk's calculations by stating in that same paragraph that certainly use of the typically used wall thickness disclosed in Schjeldahl et al with the average radius, as done in the Pinchuk Declaration would be reasonable.

As noted above, the conflicting results obtained by applying the membrane equation, and the examiner's acknowledgment that that equation "can be manipulated to produce any desired value," underscore the speculative nature upon which the determination of inherency rests.

We do not find sufficient cogent technical reasoning and/or objective evidence to support the conclusion that Schjeldahl's characterization of the catheter balloon as inelastic in the axial and radial direction *necessarily* means that the catheter balloon is biaxially oriented. The characteristic "inelastic," as employed by Schjeldahl, apparently means that the catheter balloon will expand to a preformed diameter to enable precise measurement of the pressures exerted on the inner wall of the artery during the dilation procedure (column 4 of Schjeldahl '989, lines 12 through 17).

[3] In summary, Schjeldahl does not disclose a biaxially oriented catheter balloon. We do not find a sufficient basis to support the determination that Schjeldahl's balloon is *inherently* (necessarily) biaxially oriented. *In re King, supra*; *W.L. Gore & Associates, Inc. v. Garlock, Inc., supra*; *In re Oelrich, supra*; *In re Wilding, supra*; *Hansgirg v. Kemmer, supra*. Accordingly, the examiner's rejection of claims 13, 14, 16, 17 and 25, under 35 U.S.C. §102 as anticipated by Schjeldahl is reversed. 6

The Rejection of Claims 13 through 17 under 35 U.S.C. §103 Based upon the Combined Disclosures of Schjeldahl and Wyeth.

Wyeth is directed to producing high strength biaxially oriented polyethylene terephthalate beverage containers. The disclosed method involves stretching polyethylene terephthalate having a relatively high inherent viscosity; e.g., at least about 0.85.

It is apparent from the Final Rejection and Answer that the examiner's rejection of the appealed claims under 35 U.S.C. 103 is *not* predicated upon the theory that one having ordinary skill in the art would have been led to employ Wyeth's technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter. Instead, the examiner presupposes that Schjeldahl discloses a biaxially oriented catheter balloon. The examiner relies upon Wyeth *solely* for the disclosed use of high viscosity polyethylene terephthalate tubing. We refer to page 6 of the Answer, first complete paragraph, wherein the examiner explains the rejection by stating:

Wyeth et al is not being combined with Schjeldahl et al, but merely shows the claimed high viscosity PET (polyethylene terephthalate) and supports the examiners [sic, examiner's] inherency arguments. 7 ... The examiner is not substituting the process of Wyeth et al into Schjeldahl et al since both disclose the same process. 8 Arguments that Wyeth et al can't be scaled down are irrelevant since the examiner is not seeking to scale down that reference to produce the claimed article.

[4] We have already concluded that the examiner factually erred in determining that Schjeldahl expressly or inherently discloses a biaxially oriented catheter balloon. Assuming, *arguendo*, the examiner correctly concluded that one having ordinary skill in the art would have been led to employ a high viscosity polyethylene terephthalate tubing in producing Schjeldahl's catheter balloon, the rejection under 35 U.S.C. §103 must fall because the examiner has not established that the resulting catheter balloon is biaxially oriented. *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988).

Inasmuch as the examiner's rejection under 35 U.S.C. §103 is not predicated upon the theory that one having ordinary skill in the art would have been led to employ a conventional stretch blow molding technique, such as that disclosed by Wyeth, to produce Schjeldahl's catheter balloon, the motivation for such a combination is an issue which was not crystallized on appeal and was not confronted by appellant. However, in view of the examiner's gratuitous statement in the paragraph bridging pages 5 and 6 of the Answer,⁹ we are constrained to address that issue.

There appears to be no dispute that one having ordinary skill in the art would have recognized the desirability of producing a biaxially oriented balloon for use in Schjeldahl's catheter, since biaxially oriented materials were known to exhibit high tensile strengths. The thrust of the evidence relied upon by the examiner is that one having ordinary skill in the art would have simply resorted to a conventional stretch molding technique to produce a biaxially oriented balloon for use in Schjeldahl's catheter, specifically, *the technique employed by Wyeth to produce a beverage container*. See paragraph 4 of the Rydell affidavit executed April 25, 1988 and offered in support of the protest in parent application Serial No. 914,108, paragraph 5 of the Pinchuk affidavit (Exhibit III), and paragraphs 4 and 5 of the Kaufman affidavit (Exhibit XII). Interestingly enough, *Wyeth disagrees*. See page 5 of Wyeth's declaration (Exhibit XI). Wyeth points out various differences between the PET bottles produced by his disclosed process and the requirements of a catheter balloon, and then concludes that his process could *not* be used to produce a catheter balloon of the type disclosed by Levy.

We are persuaded by Belcher's affidavits and Wyeth's declaration, notwithstanding the affidavits of Rydell, Pinchuk and Kaufman,¹⁰ that the known processes for producing

biaxially oriented beverage containers, such as that disclosed by Wyeth, could not have been simply scaled down to produce a biaxially oriented catheter balloon for use in medical dilation procedures without the exercise of inventive skill.¹¹ Based upon the record before us, it would appear unrealistic to conclude that one having ordinary skill in the art would have been led to employ Wyeth's technique, which is designed to produce beverage containers, to produce Schjeldahl's catheter balloon, motivated by a *reasonable expectation* of obtaining a . *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). The rejection under 35 U.S.C. §103 is also reversed.

REVERSED.

Footnotes

Footnote 1. Each of the Schjeldahl references contains essentially the same relevant disclosure. Accordingly, unless otherwise indicated, we have referred to these references collectively as "Schjeldahl," consistent with the approach adopted by both appellant and the examiner.

Footnote 2. See footnote 1.

Footnote 3. Schjeldahl characterizes the catheter balloon as an expander.

Footnote 4. Unless otherwise indicated, all exhibits mentioned are the exhibits to appellant's Brief.

Footnote 5. We recognize that a high burden of proof is required to demonstrate the inoperability of a United States patent. *In re Weber*, 405 F.2d 1403, 160 USPQ 549 (CCPA 1969); *In re Michalek*, 162 F.2d 229, 74 USPQ 107 (CCPA 1947). However, as noted above, Schjeldahl does not disclose a catheter balloon made of a biaxially oriented plastic. Therefore, appellant's evidence is not an attack on the operability of Schjeldahl, but quite relevant to the issue of inherency, *i.e.*, whether the catheter balloon disclosed by Schjeldahl is inherently biaxially oriented.

Footnote 6. There is evidence of record that Dupont, the assignee of the application, furnished biaxially oriented polyethylene terephthalate to Schjeldahl when he informed Dupont personnel that he required a thin, high strength polymeric film having a tensile strength in the range of 20,000-40,000 psi. See the Schjeldahl affidavit (Exhibit VIII) and the Dengler declaration executed on May 21, 1988 and appended to the protest submitted in parent application Serial No. 914,108. Such facts are not inconsistent with our determination that Schjeldahl does not disclose a biaxially oriented polyethylene terephthalate catheter balloon. The Rydell affidavit appended to the protest in the parent application does not persuade us that Schjeldahl expressly or inherently discloses a biaxially oriented polymeric catheter balloon. See Belcher's affidavit (Exhibit VI).

Footnote 7. Actually, according to the Final Rejection which is incorporated in the Answer, it is the Examiner's position that it would be *prima facie* obvious to use the high viscosity polyethylene terephthalate of Wyeth in Schjeldahl et al to produce the claimed product (page 4, the only complete paragraph).

Footnote 8. It is apparent from our reversal of the examiner's rejection under 35 U.S.C. §102 that, in our opinion, Schjeldahl discloses neither a biaxially oriented catheter balloon nor a molding process which involves stretching.

Footnote 9. The noted statement provides:

Certainly in the least there was an *invitation* to make a biaxially oriented catheter balloon at the time of the Schjeldahl et al invention. Additionally injection stretch blow molding to produce biaxially oriented articles was well known at the time of the Schjeldahl et al invention (emphasis supplied).

Footnote 10. We agree with appellant that the credentials of Belcher and Wyeth in the relevant art appear more impressive than those of protestor's experts. According to the affidavit appearing as Appendix V, Belcher authored the chapter called "Blow Molding of Polymers" for the fifth edition of the Plastic Engineering Handbook of the Society of Plastics Industry. In addition, Belcher authored two chapters, one on "injection blow molding" and one on "stretch blow molding" for the Blow Molding Handbook of the Society of Plastics and Engineers. We consider Wyeth's opinion with respect to the capabilities of his own invention entitled to greater weight than the opinions of Rydell, Pinchuk and Kaufman.

Footnote 11. We find it somewhat unrealistic in light of the apparent disparities in size and function, Belcher's affidavits and Wyeth's declaration, that Pinchuk and Kaufman equate beverage bottles to catheter balloons. See paragraph 10 of the Pinchuk affidavit (Exhibit III), wherein it is stated
s a blow molded polymeric article, a bottle and a catheter balloon are equivalent.

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See, also, paragraph 4 of the Kaufman affidavit (Exhibit XII), wherein it is stated that anyone with ordinary skill in the plastics art would know how to make a biaxially oriented PET balloon; it would be similar to making a biaxially oriented PET bottle because both catheter balloons and bottles are equivalent structures - they are both fluid containers.

- End of Case -

In re WRIGHT

(CCPA)

145 USPQ 182

Decided Apr. 15, 1965

Appl. No. 7218

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Amendments to patent application--New matter (§ 13.5)

Amendments to specification are not new matter where there merely render explicit what had been implicitly disclosed originally; all new language is not ipso facto new matter.

2. Patentability -- Anticipation -- Patents--In general (§ 51.2211)

It is no moment that reference patent has been assigned to assignee of instant application or that applicant was familiar with operation and advantage achieved by device of reference.

3. Patentability -- Anticipation -- Combining references (§ 51.205)

Fact that incorporating device of one reference patent into device of another reference patent would not provide every feature of claimed device does not meet Patent Office's position that claimed invention would be obvious to one of ordinary skill in the art with these patents before him; court is concerned with what patents disclosed, more particularly what they suggest, without regard to what patentees consider to be their inventions; issue is not whether applicant's apparatus has been fully met but whether claimed apparatus has been clearly suggested.

4. Patentability--Adding or subtracting parts (§ 51.05)

Finding that elimination of specific element and its function would be an obvious expedient is based upon a determination of obviousness under 35 U.S.C. 103, not upon a mechanical rule, which court is asked to extract from In re Karlson, 136 USPQ 184, about omission of element and its function from known combination being obvious if remaining elements perform same function as before; language to this effect in Karlson case was not intended to short-circuit wording of section 103.

5. Patentability--Aggregation or combination--In general (§ 51.151)

Patentability depends upon obviousness of overall combinations, not of individual unclaimed elements thereof.

6. Patentability--Invention--In general (§ 51.501)**Patentability--Substitution of equivalents (§ 51.65)**

Although expedients which are functionally equivalent to each other are not necessarily obvious in view of one another, they might be; where functional equivalence is not found, they may or may not be obvious; test of obviousness is applied to each set of facts as it arises.

Particular patents--Regulator

Wright, Afterburner Fuel Regulator Responsive to Compressor Discharge Absolute Pressure, claims 25 to 28 of application allowed; claims 15 to 24 refused.

Case History and Disposition:

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Appeal from Board of Appeals of the Patent Office.

Application for patent of Alexander M. Wright, Serial No. 688,459, filed Oct. 7, 1957; Patent Office Division 18. From decision rejecting claims 15 to 28, applicant appeals. Affirmed as to claims 15 to 24; reversed as to claims 25 to 28.

Attorneys:

A. M. PRENTISS, West Hartford, Conn., for appellant.

CLARENCE W. MOORE (JERE W. SEARS of counsel) for Commissioner of Patents.

Judge:

Before RICH, Acting Chief Judge, MARTIN, SMITH, and ALMOND, Associate Judges, and KIRKPATRICK, Judge.*

Opinion Text**Opinion By:**

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals, adhered to on reconsideration, affirming the rejection of claims 15 through 28 of application serial No. 688,459, filed October 7, 1957, for "Afterburner Fuel Regulator Responsive to Compressor Discharge Absolute Pressure." No claims are allowed.

The Invention

The invention relates to fuel control apparatus for aircraft turbojet engines having as "afterburner" combustion chamber, supplemental to and on the discharge side of, a "main" combustion chamber for reheating exhaust gases and thereby increasing the jet reaction thrust of the engine when maximum power output is desired, such as on take-off. As explained in the specification--

Engines of this type usually comprise, as principal elements, an air inlet, an air compressor, one or more main combustion chambers having a series of burner nozzles through which the main fuel supply is fed, a gas turbine, a supplementary combustion chamber also having a series of burner nozzles through which the supplementary fuel supply is fed, and a tail pipe for discharging the combustion gases to the atmosphere in the form of a jet. Associated with the engine are a main fuel supply system, including a fuel pump and control apparatus, for delivering fuel to the main combustion chambers, and a supplementary fuel supply system, including a fuel pump and control apparatus, for delivering fuel to the afterburners in the afterburner combustion chamber. This invention is particularly concerned with the afterburner fuel control apparatus which

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controls the afterburner fuel flow as a preselected function of the compressor discharge absolute pressure. The specification goes on to say the "invention consists in the *combination and arrangement of elements* hereinafter described and illustrated * * *." (Emphasis ours.)

Appellant's Figure 1, reproduced below since one of the two issues presented by the appeal has a direct bearing thereon, diagrammatically shows a turbojet aircraft engine with its associated main fuel supply and afterburner fuel supply system, including appellant's "control" apparatus, and the principal connections therebetween.

Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

The main elements are: a supporting casing 10, an air inlet 12, a multistage air compressor 14 having a rotor shaft 16, one of a number of main combustion chambers 18, one of a corresponding number of main fuel burner nozzles 20, connected to a generally circular fuel manifold 22 by means of a conduit 24, a multistage turbine 26 having a rotor shaft 28 connected to compressor rotor shaft 16; an afterburner combustion chamber 30, one of a plurality of afterburner fuel nozzles 32, a tail pipe 34 for discharging combustion exhaust; a center bearing 36 and end bearings 38 and 40 supported by casing 10, and a gear train 42 connected to shaft 16 for operating the fuel pumps and other accessories at a speed proportional to the engine speed.

The fuel supply system includes a supply tank 44 connected to a fuel pump unit 46 comprising a centrifugal pump 48, connected by a conduit 49 in series with a pair of parallel, positive displacement pumps 50 and 52, which supply fuel through conduits 56 and 54, respectively, to a main fuel control apparatus 58 and an afterburner fuel control apparatus 60. All three pumps 48, 50, and 52 are connected to gear train 42 as shown by the broken lines, whereby they are driven at a speed proportional to engine speed. Fuel, controlled by a pilot's manual control 62, is supplied by main fuel control 58 through conduits 64 and 24 to nozzles 20 in the main combustion chamber 18 for the operation of turbine 26; and fuel not required by the turbine is returned from main fuel control 58, through a conduit 66, to conduit 49 on the inlet side of pump 50.

Similarly, fuel at a regulated rate is supplied by the afterburner fuel control 60, through conduits 68 and 69, to afterburner nozzles 32; and fuel not required for afterburning is returned from afterburner fuel control 60, through a conduit 70, to conduit 49 on the inlet side of pump 52.

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Appellant's brief says:

As shown in Fig. 1 of the drawings * * * applicant's invention, broadly comprehended, comprises an afterburner fuel control apparatus 60, for regulating the fuel flow to afterburners 32 in afterburner combustion chamber 30, *which is used in operative association with a main fuel control apparatus 58 for regulating the fuel flow to main burner nozzles 20 in main combustion chamber 18.* [Emphasis ours.]

One of the basic requirements for fuel control apparatus for turbojet engines is that the total fuel flow to the engine should always bear a pre-selected, definite, scheduled ratio to the weight [mass?] air flow through the engine, under all operating conditions; and since the total fuel flow to the engine consists of the fuel flow to the main burners 20, and the fuel flow to the afterburners 32, the regulating of the main fuel flow by main control apparatus 58 must be fully coordinated with the regulation of the afterburner fuel flow by afterburner control apparatus 60. This coordination of fuel flows is obtained by the * * * arrangement of elements * * * shown in Fig. 1 * * *

Since one of the cardinal features of applicant's invention is regulation of the fuel flow to the main combustion chamber and the afterburner, in accordance with the rate of mass air flow through the engine, and since compressor discharge absolute pressure is a measure of said air flow, it is essential that said pressure be the sole control parameter that automatically regulates said fuel flow, because any modification of said pressure would cause said fuel flow to be not in accordance with said air flow. Since applicant's invention is particularly concerned with apparatus for regulating the fuel flow to the afterburner, the main fuel control apparatus is involved only to the extent that it cooperates in association with the afterburner control apparatus (as shown in Fig. 1), the details of construction of the main control apparatus form no part of applicant's invention, beyond the arrangement whereby (as shown in Fig. 1), it *automatically regulates the fuel flow to the main combustion chamber*, in accordance with same control parameter as the afterburner fuel control (i.e. compressor discharge absolute pressure). Accordingly, the details of construction of the main fuel control apparatus will not be further described herein since they may be any combination and arrangement of elements that operate to regulate the fuel flow to the main combustion chamber in accordance with the compressor discharged absolute pressure, as for the example of a combination and arrangement of pertinent elements similar to those of the afterburner fuel control apparatus, as hereinafter described, and illustrated in the drawings * * *.

The afterburner fuel control apparatus 60, the drawing of which is full of complex detail and not reproduced here since it is believed unnecessary for an understanding of the issues, comprises three principal parts: (1) a fuel by-pass valve which maintains a constant metering head across a variable-area, contoured, fuel metering valve; (2) the metering valve itself, together with its positioning mechanism for varying the flow area through the valve as a preselected function of the compressor discharge absolute pressure; and (3) a shut-off valve actuated by a solenoid and by a manual transfer valve, which cuts off all fuel flow to the afterburners when they are not in use.

More specifically, the afterburner fuel flows from the pump 52 to the metering valve, which is positioned as a function of the compressor discharge by means of a "nutcracker amplifier" arrangement. Any change in discharge pressure from the compressor is transmitted to a chamber in a bellows, which is opposed by a second evacuated chamber in the bellows, thereby causing movement of the bellows partition separating the two chambers. The signal thus created is transmitted to the "nutcracker amplifier," an arrangement of two parallel tracks or "links," one fixed and the other rotatable over a fulcrum in accordance with (a) tension on an adjustable spring connected to one end of the track and (b) movement of a rod connecting the other end of the track with the bellows. The amplifier actuates a rod, which moves a servo valve, which, in turn, controls the flow of fluid to one or the other side of a piston attached to the metering valve by means of a shaft. Movement of the piston thereby positions the metering valve, and the direction of movement of the piston is determined by the direction of movement of the servo valve. The direction of movement of the servo valve depends on whether an *increase* or a *decrease* in compressor discharge pressure has occurred. The amplifier also responds to a feedback signal from the metering

valve, thereby establishing

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an equilibrium in the system after each change in compressor discharge pressure.

A pressure drop regulating valve maintains the pressure drop across the metering valve constant by bypassing a certain amount of fuel around the pump 52 via conduit 70. The pressure downstream of the metering valve is sensed and the regulating valve then operates to apply the necessary correction, i.e. bypass, to establish a constant pressure differential across the metering valve. A detailed description of the structure of the pressure drop regulating valve, as well as the shut-off valve mechanism, will not be set forth.

One point of novelty in the invention is alleged to reside in the metering valve being contoured "so as to give the same difference in the rate of fuel flow for the same difference in compressor discharge absolute pressure (P_d), throughout the operating range of the engine * * *." A further point of novelty is described in the specification as follows:

One of the principal novel features of my improved afterburner fuel control is the *much higher sensitivity* in the response of the metering valve positioning means to changes in compressor discharge absolute pressure, at low values than at high values of said pressure * * *. This sensitivity performance is one of the striking features of the type of nutcracker amplifier shown in Figure 2; the advantage being approximately equal percentage sensitivity over the operating range of the fuel control. [Emphasis ours.]

The Claims

Base claim 15, upon which the remaining claims on appeal depend, reads:

15. For use with an aircraft turbojet engine having an air compressor, a main combustion chamber, a gas turbine, an afterburner combustion chamber for reheating the exhaust gases from said turbine, a fuel pump for supplying fuel to said main and afterburner chambers, and a main fuel control for automatically regulating the supply of fuel to said main combustion chamber solely in accordance with the unmodified absolute discharge pressure of said compressor; an afterburner fuel control apparatus for controlling the total flow of fuel from said pump to said afterburner chamber solely in accordance with said pressure, comprising a fuel flow metering valve, first means, actuated by said pressure, for varying the flow area through said valve solely in accordance with varying values of said pressure throughout the operating range of said apparatus; and second means for maintaining a constant metering head across said valve, throughout the operating range of said apparatus.

Claim 16 in part recites "wherein said second means includes a by-pass valve for returning fuel not passing through said metering valve to the inlet side of said pump * * *, and certain functional features of said bypass valve.

Claim 17 identifies "a movable element" as part of said "first means," e.g., the bellows partition, and also includes a "third means, actuated by said element, for varying the position of said [metering] valve * * *."

Claim 18 is dependent on claim 17 and further qualifies the "third means" by reciting means for making the ratio of incremental change in the flow area of the metering valve to the original value of the flow area a constant for a given increment of change in the position of the valve, throughout the range of movement of the valve.

Claim 19 is dependent on claim 18 and recites the contoured metering valve producing a flow which is a straightline function of the compressor discharge pressure.

Claim 20 is dependent on claim 17 and recites a "fourth means" within the third means "for amplifying the ratio between the movement of said element and the resulting movement of said valve."

Claim 21 is dependent on claim 20 and further qualifies the fourth means to include "means for restoring the equilibrium of the system * * * after any movement of said valve by said element."

Claims 22-24 are all dependent on claim 19 and add limitations relating to various manual adjustments, termed

in the specification "factory adjustments" and a "Field Slope Adjustment." These adjustments do not change during flight, but do affect the overall performance of the aircraft while in flight.

Claims 25-28 have been rejected solely on the ground they include matter for which there is allegedly no basis in the original disclosure. At one time these claims were deemed allowable, but the allowance was withdrawn by reason of an amendment to base claim 15.

The New Matter Rejection

During prosecution, in an effort to overcome a rejection on prior art, appellant amended claim 15 to include the terms "solely" and "unmodified" (first

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occurrences only) in describing the manner of fuel control for the main combustion chamber. The examiner raised the objection of lack of antecedent basis in the original disclosure, and an issue arose which the board discussed as follows:

The essential issue with respect to the rejection of the claims as based on an inadequate disclosure, and the rejection of the claims on the prior art relates to the nature of the control parameter. It is strongly urged by appellant that the limitations relating to the feature that the fuel controls are automatically regulated "solely in accordance with the unmodified absolute discharge pressure of said compressor" represent the exact nature of appellant's control parameter that determines the basic philosophy and fundamental mode of operation of his invention.

We agree with the examiner that the original specification and drawings do not show any details of the main fuel control whereby only unmodified absolute discharge pressure regulates the main fuel supply. While the original disclosure did state that the fuel is regulated in accordance with the rate of mass air flow through the engine as measured by the compressor discharge absolute pressure, we find no statement that it is solely so regulated and that other parameters, such as fuel pressure do not modify it. The examiner has called attention to the patent to Lee, which shows that additional control parameters may be used in a fuel control.

While the prior art does not show the main fuel control automatically regulated solely in accordance with the unmodified absolute discharge pressure, we do not give this limitation any patentable weight since the limitations of "solely" and "unmodified" are not supported in the original disclosure. There being no basis in the original disclosure for the limitations which are now urged to be critical, we do not consider such limitations as being of patentable significance in the claims of this application.

We believe the examiner and board have misconstrued at least two portions of the original disclosure.

First, Fig. 1 shows the discharge pressure of compressor 14 to be transmitted unmodified from chamber 76 through conduits 74 and 72 to both the main fuel control 58 and the afterburner fuel control 60. No alterations to this pressure are shown. The drawing communicates as clearly as possible the idea of transmitting *unmodified* compressor discharge pressure to the respective fuel control apparatuses. The figure clearly shows that the only control entity, other than discharge pressure, is a manual control 62, which is applied to the main fuel control apparatus 58, but this feature has nothing to do with appellant's invention. Of course, the aircraft is subject to various pilot *controls*, including fuel control, at times such as on take-off and landing, but appellant's invention is concerned with *regulating* the fuel as a function of mass air flow through the compressor during flight. As the mass air flow changes, for example by a change in altitude or for any other reason, the rate of fuel flow to the main burner and to the afterburner is adjusted accordingly. Furthermore, this "regulating" is shown to be *automatic* since it occurs without the aid of external manual influences.

Second, we believe the board erred in misconstruing the following passage from the specification, which all agree constituted a portion of the *original* disclosure:

Both the main and afterburner fuel controls are connected by conduits 72 and 74 with the compressor discharge chamber 76, whereby *the fuel supplied by both controls is regulated in accordance with the rate of mass air flow through the engine, as measured by the compressor discharge absolute pressure (P_d) in chamber 76.*

[Emphasis ours.]

We understand this statement to say that the fuel flow to the engine from both control apparatuses 58 and 60 is automatically regulated (as distinguished from the manual control 62) by the *same* control parameter and that this parameter is compressor discharge absolute pressure. Since the compressor discharge pressure is transmitted *unmodified* from chamber 76 to *both* control apparatuses 60 and 58, it follows that fuel flow *to the engine* from both apparatuses is automatically regulated by unmodified, compressor discharge absolute pressure.

We believe further that appellant's specification as filed discloses that fuel flow to the engine is automatically regulated *solely* by unmodified, compressor discharge absolute pressure. Whereas the board fails to find any statement that it is so regulated and that other parameters, such as fuel pressure, do not modify it, we fail to find that such other

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parameters are at all intended to be included. To assume that parameters, other than compressor discharge absolute pressure, *may* control the fuel flow in appellant's invention, is to indulge in unwarranted speculation. Appellant's drawings do not show them, the specification does not describe them or even suggest that they are present, and we are not willing to conclude that they are. To do so would be asking future applicants to expressly negate all features which, although perhaps common in the art, are not intended to be part of the disclosure. Considering the overall operation of the invention, as *originally* disclosed in the specification and drawings, we agree with appellant that the regulation of fuel flow *solely* by unmodified, compressor discharge pressure was inherently disclosed therein.

In summary, finding no basis in the original specification or drawings to indicate that appellant intended either fuel control apparatus to be *regulated*, as opposed to being controlled which is what manual device 62 does, in any way other than *automatically* and by any parameter other than *unmodified* compressor discharge absolute pressure, we hold that these concepts were inherently disclosed in the application as filed and the rejection of claims 15-28 on grounds of inadequate disclosure is reversed.

[1] An ancillary matter is the question of the propriety of the examiner's and board's refusal¹ to enter appellant's proposed amendment of December 16, 1960. The full text of the change sought to be effected by this amendment does not appear in the printed record, and some confusion exists as to the relationship of this amendment to an amendment filed by appellant on October 3, 1960. The October 3 amendment also contained additions to the specification, some or all of which are printed in the record as part of the specification and which the solicitor's brief, in a footnote, refers to as "prejudicial to the Commissioner's new matter position * * *." Under the circumstances, we are unable to rule specifically on entry of the December 16, 1960 amendment per se. However, we have studied the four passages, indicated in the solicitor's brief as having been stipulated as not part of the original specification, but which nevertheless appear in the record, and conclude that these passages do *not* add "new matter" to the specification. We reach this conclusion primarily for the reasons above indicated in regard to the amendment of base claim 15 to recite the terms "solely" and "unmodified." We feel that the amendments to the specification merely render explicit what had been implicitly disclosed originally, and, while new *language* has certainly been added, we are not prone to view all new "language" ipso facto as "new matter."

The Art Rejection

Claims 15-24 were rejected as unpatentable over various combinations of the following prior art:
Hooker, 2,555,445, June 5, 1951.

Mock, 2,581,275, Jan. 1, 1952.
Lee II, 2,675,674, Apr. 20, 1954.
Chandler et al., 2,700,275, Jan. 25, 1955.
Davies et al. 2,742,755, Apr. 24, 1956.
Watson et al., 2,764,868, Oct. 2, 1956.
Thorpe et al., 2,841,957, July 8, 1958.
Porter, 2,909,896, Oct. 27, 1959.

The principal rejection is that of base claim 15 "as being unpatentable over Chandler in view of Davies."

Chandler shows a turbojet engine arrangement generally similar to that in appellant's Fig. 1. The respective fuel flows to the engine from the main fuel control and from the afterburner fuel control are *regulated* in accordance with the pressure *rise* across the air compressor. In the afterburner fuel control, the fuel flow to the engine is regulated by a valve which functions in accordance with changes in this pressure rise. The pressure differential across the valve itself is maintained constant by means of another valve whose operation is subject to this pressure differential and a constant rate spring.

Davies is directed to a fuel system for pilot burners in gas-turbine engine reheat equipment and shows controlling the total fuel flow to an afterburner in response to compressor discharge pressure which, in turn, is shown to be a *function* of the mass air flow through the engine. Appellant agrees with this analysis of Davies but contends, *inter alia*, that Davies does not thereby show total fuel flow to his afterburner in *accordance with* compressor

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discharge pressure, presumably meaning "solely" in accordance with this pressure.

In regard to the art rejection, the board said:

The rejection of the claims as being unpatentable over the prior art is based essentially on the combination of the Chandler et al. and Davies et al. patents. The principal distinction over the Chandler et al. patent resides in the fact that in Chandler et al. the main fuel and afterburner fuel controls are automatically actuated in response to the difference between the pressure discharge and inlet pressures, whereas in the instant application appellant uses the parameter of absolute compressor discharge pressure to control fuel flow. The examiner held that the distinction between these two control parameters was not patentable especially in view of Davies et al. Davies et al. show the expedient of controlling afterburner fuel flow by absolute compressor discharge pressure.

We agree with the examiner that it would not be patentable to utilize absolute compressor discharge pressure as suggested by Davies et al. in lieu of the pressure rise control signal in Chandler et al.

In response, appellant argues in his main brief that the substitution of absolute compressor discharge pressure, *as employed by Davies*, for the pressure rise across the compressor as employed by Chandler to automatically regulate the fuel flow to the afterburner would not result in a fuel control apparatus meeting the terms of the claims. We note that all the comparisons there made, showing novelty of the present invention, are made between the claims on appeal and Davies. Appellant also argues that one of the cardinal features of his invention is a "marked *simplification* of afterburner fuel controls, in comparison with most of the prior art" by eliminating *fuel pressure* as a parameter for regulating fuel flow to an afterburner, as employed by Davies for example. It is not until we approach the end of the brief that we find any attempt to establish patentability over Chandler, the primary reference. Appellant there says:

(5) The first substantial step in simplifying afterburner controls was achieved by the Chandler patent of record, which eliminated *fuel pressure*, as a parameter for regulating afterburner fuel flow, by using a combination of *air* pressures (i.e. the pressure *rise* across the compressor), to regulate afterburner

fuel flow.

The second substantial step in simplifying afterburner fuel controls was achieved by applicant's invention, which *eliminated compressor inlet air pressure as a factor* in the *parameter* for afterburner fuel regulating, thus leaving only *one* air pressure line from the compressor to the regulator.

(6) The Chandler patent of record, is assigned to the same assignee as the application involved in the appeal at bar, and applicant was familiar with the operation and advantage achieved by the Chandler fuel control. The objective of *further simplifying* Chandler's control was clearly not to be found in turning back to prior art devices, such as Davies, which used *fuel pressure*, as well as compressor pressure, as parameters to regulate afterburner fuel flow, since such prior art controls were obviously far more complicated than Chandler's control.

[2] First, it is of no moment that the Chandler patent has been assigned to the assignee of the subject application or that appellant was actually familiar with the operation and advantage achieved by the Chandler fuel control. Second, we do not understand appellant's contention that simplification of Chandler's control could not be found in turning "back" to devices such as Davies for the Davies patent was applied for in 1950, nearly two years after Chandler filed, and issued approximately 15 months after the Chandler patent issued. In any case, both patents are prior art and must be considered together. To be sure, Davies' device may be more complicated than Chandler's in certain respects, but we believe appellant has overlooked other disclosures in Davies which, in our opinion, *suggest* the claimed invention.

Appellant says, in effect, that following the "first substantial step" in simplifying fuel controls taken by Chandler, that of eliminating fuel pressure as a parameter, the next substantial step was the present invention which, stripped to its fundamentals, is apparatus using absolute discharge pressure as a sole parameter in regulating fuel flow, and that this latter step was unobvious.

We cannot agree with the contention that appellant's invention was unobvious. Davies says:

It is known that when a sonic velocity occurs in the turbine nozzles of a gas-turbine engine, *the mass flow*

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*of air which passes through the engine is proportional to the absolute delivery pressure of the compressor of the engine if the turbine inlet temperature is constant * * *. [Emphasis ours.]*

Davies goes on to say:

Since in preferred arrangements according to the invention, the fuel delivery to the pilot burner is proportional to the absolute delivery pressure of the compressor, it is also proportional to the mass flow of air flowing through the engine * * *.

[3] While appellant is correct in contending that incorporating the Davies *device* into the Chandler *device* would not provide every feature of the claimed device, we believe this contention fails to meet the issue before us. The Patent Office position is that the claimed invention would be obvious to one of ordinary skill in the art with the Chandler and Davies patents before him. Hence, we are concerned with what these patents *disclose*, more particularly what they suggest, without regard to what the respective patentees consider to be their inventions. The issue is not whether appellant's apparatus has been "fully met" but rather whether the claimed apparatus has been clearly suggested. We believe it has, since the quoted passages from Davies tell one of ordinary skill in the art that compressor discharge pressure can be used to regulate automatically fuel flow in accordance with mass air flow through the engine.

[4] Finally, we believe the word "solely" does not so limit claim 15 as to render it patentable. The afterburner fuel control of Chandler is governed by two parameters, pressure differential across the compressor and tail pipe temperature. We agree with the solicitor that "the elimination of the temperature parameter for the afterburner fuel

control of Chandler * * * together with its tailpipe safeguarding function, would be an obvious expedient," but we hasten to add that this finding is based upon a *determination of obviousness under section 103* and not upon a mechanical rule, which the solicitor would have us extract from *In re Karlson*, 50 CCPA 908, 311 F.2d 581, 136 USPQ 184 , about the omission of an element and its function from a known combination being obvious if the remaining elements perform the same function as before. Language to this effect in Karlson was never intended to short-circuit the clear wording of 35 U.S.C. 103. The same reasoning applies to the word "solely" in describing the regulating of fuel flow to the main combustion chamber.

Claims 16 and 17 were rejected "for substantially the same reasons as claim 15 * * * in view of Thorpe who teaches using a by-pass valve * * *, the specific features of this valve being set forth and allegedly teaching appellant's modifications of the apparatus defined by claim 15. Claims 18, 19, and 24 were rejected for substantially the same reason as claim 17 "in view of Mock"; claims 20 and 21 were rejected for substantially the same reasons as claim 17 "in view of Watson"; and claims 22 and 23 were rejected for substantially the same reasons as claim 19 "in view of Hooker." The Lee patent was used to provide a more detailed analysis of a main fuel control apparatus, Chandler's main fuel control having been indicated as corresponding to that of Lee's. The Porter reference appears to have been dropped after the final rejection. Each additional reference was used to provide either a teaching or suggestion of the particular modification of the base claim, or to show that such modification constitutes "merely a matter of design choice."

The examiner's answer says:

Applicant relies on the patentability of the base claim 15 to determine the patentability of claims 16-24 over the art as applied. Throughout the prosecution of the case applicant has followed this same approach and this is taken by the examiner to be an acquiescence to the propriety of the application of these additional references as used against claims 16-24. Accordingly, no additional comment is directed by the examiner as concerns the art rejection of claims 16-24.

While we note that appellant strongly disagrees with the examiner that he has at any time, up to and including the present appeal, *acquiesced* in the propriety of treating all of claims 15-24 together as regards their patentability over the art, we also note that appellant has failed to come forth with an affirmative argument as to why any or all of claims 16-24 are patentable, independently of the patentability of claim 15. Some effort along these lines is demonstrated in appellant's brief before the board, but these arguments for the most part boil down to a reliance on the patentability of base claim 15.

[5] We certainly agree with appellant, however, that claims 16-24 do not *claim the additional feature*, but instead define *combinations*, the combinations being made up of the apparatus set

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forth in the base claim *and the additional feature*. Patentability depends on the obviousness of the overall *combinations*, not of the individual *elements* of that combination for *they* are not being claimed. We do not agree with appellant, however, that these features are sufficient to render the otherwise *un* patentable combination defined by claim 15 patentable.

Appellant, at oral argument, relied heavily on our decision in *In re Flint*, 51 CCPA 1230, 330 F.2d 363, 141 USPQ 299 , and suggests that we examine the present appeal in light of our decision and rationale there. In Flint the invention related to a releasable hold open device for doors which the examiner and board found to be "functionally equivalent" to the prior art device. The appellant therein contended that such a finding, even if correct, did not necessarily render the claimed device unpatentable since the *statutory* test is the obviousness, under 35 U.S.C. 103, of the novel subject matter and not whether the invention is "functionally equivalent" to the art device. We agreed with that contention, saying, 141 USPQ at 302:

Assuming, arguendo, that the pin ejection system of appellant and the releasable spring arm taught

by Pollack are "functionally equivalent," it does not follow that the former would be "obvious" to one of the ordinary skill in view of the latter. On the contrary, we see no suggestion in Pollack's leaf spring arm and stud construction to employ a spring-loaded pin *directly in the pivot socket* even though the solicitor characterizes such construction as "a slightly different disposition of the pin member" which results in a combination which is "merely the obvious equivalent of that of Pollack." We therefore do not find obviousness.

[6] In Flint we also said, citing *In re Scott*, 51 CCPA 747, 323 F.2d 1016, 139 USPQ 297, that "Expedients which are functionally equivalent to each other are not necessarily obvious *in view of* one another." On the other hand they *might* be, and, of course, where "functional equivalence" is not found, they may or may not be obvious. The test of obviousness, therefore, is to be applied to each set of facts as it arises. Under the facts of *this* case, we hold that claims 15-24 define subject matter which *is* obvious within the meaning of section 103.

The rejection of claims 15-28 on the ground of inadequate disclosure is *reversed* and the rejection of claims 15-24 as unpatentable over the art is *affirmed*.

Footnotes

Footnote 1. The examiner's refusal led to the filing of a Petition to the Commissioner, which was denied. Ultimately a second Petition to the Commissioner was filed, in response to which the matter was said to be fully covered by section 608.04(c) of the Manual of Patent Examining Procedure, which says, in effect, that where the alleged new matter is "introduced into" or "affects" the claims, thus necessitating their rejection, the question becomes an appealable one, and should not be considered on petition even though that new matter has been introduced into the specification.

Footnote * United States Senior Judge for the Eastern District of Pennsylvania, designated to participate in place of Chief Judge Worley, pursuant to provisions of Section 294(d), Title 28, United States Code.

- End of Case -

In re NATHAN, HOGG, AND SCHNEIDER

(CCPA)

140 USPQ 601

Decided Mar. 12, 1964

Appl. No. 7145

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Amendments to patent application--New matter (§ 13.5)

Subsequent clarification of or a change in original disclosure does not necessarily make that original disclosure fatally defective; thus, amendatory material is not new matter where it is concerned with an inherent characteristic of an illustrative product of applicants' invention already sufficiently identified in original disclosure.

Particular patents--Steroids

Nathan, Hogg, and Schneider, Steroids, claims 1 to 16 of application allowed.

Case History and Disposition:

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Appeal from Board of Appeals of the Patent Office.

Application for patent of Alan H. Nathan, John A. Hogg, and William P. Schneider, Serial No. 759,400, filed Sept. 8, 1958; Patent Office Mechanized Division A. From decision rejecting claims 1 to 16, applicants appeal. Reversed.

Attorneys:

EUGENE O. RETTER and G. A. BLAUFARB, both of Kalamazoo, Mich., for appellants.

CLARENCE W. MOORE (J. E. ARMORE of counsel) for Commissioner of Patents.**Judge:**

Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, Associate Judges.

Opinion Text**Opinion By:**

MARTIN, Judge.

This appeal is from a decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims 1 through 16 of appellants' application serial No. 759,400, filed September 8, 1958 for "Steroids." No claim has been allowed.

The appealed claims are directed to certain 2-halo (fluorine or chlorine) steroids, the compound 2-halo (fluoro- or chloro-) 17 α , 21-dihydroxy-4-pregnene-3,20-dione being representative of the claimed compounds. All the claims further, as the result of an amendment entered during prosecution of the application before the Patent Office, specify the alpha (α) orientation for the 2-halo substituent.

The relationship of the 2-halo atom to the steroid nucleus of the claimed steroids can be represented diagrammatically as:

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

The 2-position of the molecule of appellants' steroids is represented by saturated carbon atom C₂. Saturated carbon atom C₂ is bonded to saturated carbon atoms C₁ and C₃, to the hydrogen substituent and to the fluorine or chlorine substituent.

Appellants point out that because of the relation of the valence bond angles of the saturated carbon atoms of the steroid, one of the two substituents attached to saturated carbon atom C₂ will project toward one side of the approximate plane of the steroid nucleus and the other substituent toward the other side of that plane. The substituent which projects toward the opposite side from the angular methyl groups (carbon atoms C₁₈ and C₁₉) is said to have the alpha orientation, whereas the substituent projecting toward the same side from the angular methyl group is said to have the beta orientation.

The record shows that on June 15, 1959 appellants amended their specification and claims to indicate that the 2-halo steroids of their invention had the alpha orientation. This amendment was in response to the examiner's first action on the claims. That action, according to the examiner's answer, "merely rejected the claims as unduly broad and indefinite in failing to give the configuration (alpha or beta) of the 2-halo atoms." On June 2, 1960 appellants submitted an affidavit under Rule 132 in support of the propriety of their amendment, which affidavit reads in part:

That, the synthesis of the steroid compounds accomplished in the course of completing the invention described and claimed in the above-identified application involved, in the case of the 2-fluoro compounds, the introduction of a fluorine atom in the 2-position of a certain Δ 4-3-keto steroid of the pregn α ne [sic] series; namely, an alkali metal enolate of 2-alkoxy-oxalyl-11 β 21-dihydroxy-4, 17(20)-[cis]-pregnadien-3-one (Preparation 6 of the specification) by reaction with perchloryl fluoride to produce 2-fluoro-2-alkoxyoxalyl-11 β , 21-dihydroxy-4,17 (20)-[cis]-pregnadien-3-one;

That, this latter compound was then converted to a 2-fluorinated-11 β , 21-dihydroxy-4,17(20-[cis]-pregnadien-3-one (the product of Preparation 6 of the specification);

That, we are aware of the work of others wherein a fluorine substituent has been introduced by the

reaction of perchloryl fluoride upon the 2-alkoxy-oxalyl substituted Δ 4-3-keto steroid (Kissman et al., J.A.C.S. 81:1262); * * * and we are moreover aware that in * * * [that work] the stereo-configuration of the 2-fluorine substituent is designated as the α -configuration based, * * * upon physical evidence consistent with such a con-

Page 603

figuration; and moreover we are unaware of any facts inconsistent therewith;

That, we converted the product of Preparation 6 of the specification to 2-fluoro hydrocortisone acetate by the process of Preparation 7 and Example 1 and that we hydrolyzed the product of Example 1 by the process of Example 6 thus producing 2-fluoro hydrocortisone;

That, in the case of the Kissman et al. work, we have made a comparison and found that our 2-fluoro hydrocortisone, prepared by the hydrolysis of the product of Example 1 of the specification and have found physical characteristics consistent with and no physical characteristics inconsistent with the identity thereof;

That, these physical constants are:

For the 2-fluoro hydrocortisone prepared by hydrolysis of our Example 1 by the process of Example 6 of the specification:

Conjugated ketone band at 5.97 μ . λ_{max} at 242 m μ , E 14,200 (in ethanol). αD plus 185 degrees (methanol). Melting point 212-221 degrees centigrade.

The physical characteristics reported by Kissman et al. are:

Conjugated ketone band at 5.87 μ . λ_{max} 241m μ , E 14,800. αD plus 190 degrees (methanol). Melting point 216-220 degrees centigrade.

That, the product of our Example 6 is identical with the product designated as 2 α -fluoro hydrocortisone of Kissman et al.;

That, the subsequent chemical conversions to which the compounds disclosed and claimed in the above-identified application for patent are subjected do not alter the stereoconfiguration of the 2-fluoro substituent;

In rejecting the claims, the examiner took the position that the alpha configuration of the 2-halo substituent is not inherent in the compounds disclosed in the case as originally filed and since the configuration of the 2-halo substituent was not included in the application as filed, it may not be entered at a later date.

The board held that amendatory material, designating the 2-halo substituent as alpha oriented, has no basis in the original disclosure and thus is in violation of the last sentence of 35 U.S.C. 132¹ which prohibits the introduction of new matter. The board was not convinced of any error in the examiner's rejection and stated that it was "not satisfied that extraneous evidence discovered after the filing of the application can be used as support for a stereoconfiguration not originally disclosed." Regarding the Rule 132 affidavit the board stated:

The difficulty with the Rule 132 affidavit is that appellants attempt to identify their compounds on the basis of the knowledge of others acquired after the filing date of the instant application. * * *

Appellants urge that the application as filed taught those skilled in the steroid art how to prepare and identify the claimed 2-halo steroids and that accordingly the amendatory material does not constitute new matter. It is contended that the amendment merely defines more precisely for those skilled in the art the 2-halo steroids inherently produced by the process of the application as filed and identified therein by physical characteristics.

It seems to us that the issue here is whether appellants' identification of their 2-halo steroids in their original disclosure is adequate to identify the claimed subject matter and whether there is sufficient evidence in the record to show the alpha orientation to be an inherent characteristic of the subject matter so identified. If the answers are in the affirmative then appellants' amendment specifying the alpha orientation for the 2-halo substituent is not new

matter but rather is merely a statement of an inherent property of the steroids as disclosed in appellants' original disclosure.

[1] A subsequent clarification of or a change in an original disclosure does not necessarily make that original disclosure fatally defective. This court in *Reister v. Kendall*, 34 CCPA 859, 159 F.2d 732, 72 USPQ 481, dealt with an interference in which a count was directed to certain dyestuffs. Appellee relied on a British provisional specification for constructive reduction to practice although the structural formulae

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given for the identification of the respective products of the reaction in appellee's British specification *differed* from the corrected formulae for the same products recited in his U.S. application. The board nevertheless, in finding for appellee, held that his British specification disclosed the dyestuffs and the means for identifying them irrespective of the wrong formulae and thus was a sufficient disclosure of the patentable subject matter. This court found no error in the board's decision.

We think appellants' identification of their 2-halo steroids in their original disclosure sufficiently identifies the claimed subject matter. Appellants' original disclosure was specifically directed to a generic class of 2-halo steroids which steroids were chemically named, no question being presented as to their nomenclature aside from the orientation of the halogen at the 2-position of the steroid nucleus. Appellants' Example 1, which is stated in the application to be illustrative of the "products of the present invention," gave a definite melting point range, optical rotation, ultraviolet spectral analysis and chemical analysis for the product obtained therein. Appellants have further shown through an affidavit that the hydrolysis² of the product of their Example 1 of their application yields a 2-fluoro hydrocortisone which has physical constants consistent with a product designated in the art as 2 α -fluoro hydrocortisone. Such evidence, we think, is adequate to demonstrate an inherent characteristic (the alpha orientation) of appellants' claimed subject matter.

Thus, we consider that the amendatory material of June 15, 1959 is concerned with an inherent characteristic of an illustrative product of appellants' invention already sufficiently identified in appellants' original disclosure as filed. Such amendment is not prohibited by the statute. In *Ex parte Davisson and Finlay*, 133 USPQ 400, 402, for example, the board noted that the examiner had entered an amendment reciting the optical rotation data and elemental analysis of the sulfate of a claimed substance as well as the spectroscopic characteristics of the claimed substance "apparently regarding them as a statement of inherent properties of the material adequately disclosed" in an original disclosure and stated that it saw no reason for "taking a different view of the matter." We think the case at bar presents an analogous situation.

For the foregoing reasons, the decision of the board is *reversed*.

Footnotes

Footnote 1. 35 U.S.C. 132 reads:

Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Commissioner shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

Footnote 2. Appellants have stated in their affidavit that the subsequent chemical conversions of their Example 1 compound do not alter the stereoconfiguration of the 2-fluoro substituent and there is nothing in the record to controvert that statement.

- End of Case -

In re MAGERLEIN AND SCHNEIDER

(CCPA)

145 USPQ 683

Decided June 14, 1965

Appl. No. 7148

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Affidavits--In general (§ 12.1)

Rule 132 affidavit offered to show inherency should be considered on the merits even though it was based on the work of another subsequent to filing of application.

2. Court of Customs and Patent Appeals--Dismissing and remanding (§ 28.15)

Court of Customs and Patent Appeals--Issues determined--Ex parte patent cases (§ 28.203)

It is not appropriate for court to consider sufficiency of Rule 132 affidavit to establish inherency since court is without the benefit of views of Patent Office and applicants on technical questions presented therein; rejection is reversed and case is remanded for further proceedings in Patent Office.

Particular patents--Organic Compounds

Magerlein and Schneider, Organic Compounds and Process, rejection of claims 1, 3 to 6, and 8 to 16 of application reversed.

Case History and Disposition:

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Appeal from Board of Appeals of the Patent Office.

Application for patent of Barney J. Magerlein and William P. Schneider, Serial No. 776,437, filed Nov. 26, 1958; Patent Office Mechanized Division A. From decision rejecting claims 1, 3 to 6, and 8 to 16, applicants appeal. Reversed.

Attorneys:

EUGENE O. RETTER and GERARD A. BLAUFARB, both of Kalamazoo, Mich., for appellants.

CLARENCE W. MOORE (RAYMOND E. MARTIN of counsel) for Commissioner of Patents.

Judge:

Before RICH, Acting Chief Judge, and MARTIN, SMITH, and ALMOND, Associate Judges.

Opinion Text

Opinion By:

MARTIN, Judge.

This is an appeal from the decision of the Board of Appeals which affirmed the examiner's rejection of claims 1, 3-6 and 8-16 of appellants' application ¹ for "Organic Compounds and Process."

The appealed claims are directed to certain 16-hydroxy steroids. As the result of an amendment filed during prosecution of the application before the Patent Office, all claims now specify the alpha (α) orientation for the 16-hydroxy substituent. Claim 1 is representative:

1. A compound of the following formula:

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

wherein X is selected from the group consisting of the carbonyl radical and the β -hydroxymethylene radical, R and R' are selected from the group consisting of hydrogen and acyl radical of a hydrocarbon carboxylic acid containing from 1 to 12 carbon atoms, inclusive, and wherein, when R is acyl, R' is acyl.

The relationship of the 16-hydroxy substituent to the steroid nucleus can be represented diagrammatically as:
Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

The dotted line used to illustrate the bond joining the hydroxy substituent (R=H) to the steroid nucleus in claim 1 above is a convention adopted by steroid chemists to denote that the

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hydroxy group has the α orientation or configuration.²

The examiner initially rejected the claims as based on insufficient disclosure, noting that neither the specification nor claims as filed disclosed whether the 16-hydroxy substituent is α or β oriented. In response, appellants amended the specification and claims to indicate that the hydroxy substituent had the α orientation. The examiner then rejected the claims as containing new matter. One of the appellants submitted an affidavit under Rule 132 in support of the propriety of their amendment. The affidavit attempts to compare compounds assertedly Copyright 2004, The Bureau of National Affairs, Inc. Reproduction or redistribution, in whole or in part, and in any form, without express written permission, is prohibited except as permitted by the BNA Copyright Policy.

produced by appellants' disclosed process with a compound having known 16α configuration referred to as the Bernstein et al. compound. The affidavit reads in part:

That, he has studied and is familiar with the work of Bernstein et al. [J. Am. Chem. Soc., 81, 1689 (1959)] on 16α -hydroxylated steroids and is in agreement with reported structures;

That, he knows of no facts or principles of structural chemistry which are inconsistent [sic] with the 16α -configuration of Bernstein's compound, 11β , 17α -dihydroxy- 16α , 21-diacetoxy-1,4 pregnadiene-3,20-dione;

That, he has reproduced Bernstein's identical compound, 11β , 17α -dihydroxy- 16α 21 - diacetoxy - 1,4 - pregnadiene-3,20-dione;

That, he made the structural assignment of 11β , 16α -dihydroxy-21-acetoxy-4,17 (20)-pregnadiene-3-one ³ on the basis of the above considerations and the following chemical reactions which were carried out by him and under his direction:

The affidavit continues with a flow sheet and detailed description of the reactions carried out. The analytical comparative data was listed in preparation 3 of the affidavit:

* * * Recrystallization from ethyl acetate gave 11β , 17α -dihydroxy- 16α , 21 - diacetoxy - 1,4 - pregnadiene - 3,20-dione (IV) melting at 162-165° C. (solvated), ν max. 3440, 1743, 1665, 1625, 1610, 1237, 1050 cm ⁻¹.

Bernstein et al., J. Am. Chem. Soc., 81, 1689 (1959) discloses 11β , 17α -dihydroxy- 16α , 21-diacetoxy-1, 4-pregnadiene-3,20-dione melting at 161-163° C., max. 3458, 1748, 1668, 1632, 1612- (shoulder), 1234, 1060 cm ⁻¹. ⁴

The affidavit concluded:

That, the 11β , 17α -dihydroxy- 16α , 21-diacetoxy-1, 4-pregnadiene-3, 20-dione (IV) prepared in Preparation 3, above, was identical in melting point and infrared analysis to a sample of 11β , 17α -dihydroxy- 16α , 21-diacetoxy-1, 4-pregnadiene-3, 20-dione known to be identical with the 11β , 17α -dihydroxy- 16α , 21-diacetoxy-1, 4-pregnadiene-3, 20-dione reported by Bernstein et al., J. Am. Chem. Soc., 81, 1689 (1959);

That, from the above experimental data it is his opinion and belief that the introduction of a 16α -hydroxyl group via the selenium dioxide process of Preparations 1 and 5, above, and Examples 1 and 4 of application Serial No. 776,437, is inherently productive of compounds containing the 16α -configuration;

That, in the above series of chemical reactions, Preparations 1 through 5, and in the chemical transformations of application Serial No. 776,437, Examples 1 through 6, there are no conditions which would lead to the epimerization of the 16α -substituent and therefore the 16α -position in all instances has the α -configuration;

Appellants urge that our decision in In re Nathan, 51 CCPA 1059, 328 F.2d

1005, 140 USPQ 601 , is dispositive of the issue in this case. There, the appellants found themselves in a similar predicament when the examiner and board refused to recognize an amendment and affidavit establishing the orientation of a 2-halo substituent in a steroid molecule as inherently α . We said in Nathan, 140 USPQ at 603:

It seems to us that the issue here is where appellants' identification of their 2-halo steroids in their original disclosure is adequate to identify the claimed subject matter and whether there is sufficient evidence in the record to show the alpha orientation to be an inherent characteristic of the subject matter so identified. If the answers are in the affirmative then appellants' amendment specifying the alpha orientation for the 2-halo substituent is not new matter but rather is merely a statement of an inherent property of the

steroids as disclosed in appellants' original disclosure.

We think that statement is equally applicable to the factual situation here. On the first point, we are satisfied that appellants' original disclosure adequately identifies the claimed subject matter. The disclosure is specifically directed to a class of 16-hydroxy steroid compounds, no question being presented as to the nomenclature employed to identify the compounds aside from the orientation of the hydroxy group at the 16-position of the steroid nucleus. There appears no reason to doubt that one skilled in the art following the teaching of the application would be able to produce those compounds and identify them as 16-hydroxy steroids.

The remaining question is whether there is sufficient evidence in the record to show the α orientation to be an inherent characteristic of the subject matter so identified. Appellants rely on their Rule 132 affidavit to establish inherency. In particular, appellants state that the affidavit comparison of the melting points and infra-red analyses of the compound of preparation 3, supra, and Bernstein's 11 β , 17 α -dihydroxy-16 α ,21-diacetoxy - 1, 4 - pregnadiene - 3,20-dione compound of known 16 α -hydroxy configuration establishes inherency of the 16 α -hydroxy orientation in their compounds. Appellants further rely in part on comparative paper chromatographic analyses of other compounds prepared in the affidavit.

[1] The issue of whether the synthesis routes and comparative data shown in the affidavit are sufficient to establish inherency of the 16 α -hydroxy configuration as produced by the disclosed process from the disclosed reactants was not considered by the board, nor is it discussed to any great extent in appellants' brief here. In its decision, rendered prior to this court's opinion in Nathan, the board apparently thought it unnecessary to consider the merits of the affidavits since "it was based on the work of another subsequent to the filing date of the application." For the reasons stated in Nathan we do not consider the board's position to be sound.

[2] Under the circumstances, however, we do not think it is appropriate for us to consider the sufficiency of the affidavit without the benefit of the views of the Patent Office and appellants on the technical questions presented therein. Thus we do not decide the question of whether the affidavit process and, for example, the comparative melting point data and infra-red analysis of the affidavit are sufficient to establish the inherency of the 16 α orientation as opposed to 16 β orientation. Nor do we decide whether other process routes or additional analytical data, such as optical rotation, might be required. Accordingly we are obliged to *reverse* and *remand* this case for further proceedings in the Patent Office not inconsistent herewith.

Footnotes

Footnote 1. Serial No. 776,437, filed Nov. 26, 1958.

Footnote 2. Saturated carbon atom C ₁₆ is bonded to carbon atoms C ₁₅ and C ₁₇, to the hydroxy substituent, and to a hydrogen atom. Appellants point out that because of the relation of the valence bond angles of saturated carbon atoms, one of the hydrogen or hydroxy substituents attached to C ₁₆ will project toward one side of the approximate plane of the steroid nucleus and the other substituent toward the other side of that plane. The substituent which projects toward the opposite side from methyl groups C ₁₈ and C ₁₉ is said to have the α orientation, whereas the group projecting toward the same side of the nucleus as the methyl groups is said to have β orientation.

Footnote 3. One of appellants' claimed compounds, corresponding to Example 1 of the specification.

Footnote 4. The record does not show what technique Bernstein employed to introduce the 16 α -hydroxy group into the steroid nucleus. Bernstein dehydrogenated 11 β , 16 α , 17 α , 21 - tetrahydroxy - 4 - pregnene - 3, 20-dione (16 α -hydroxy hydrocortisone) to give 11 β , 16 α , 17 α , 21-tetrahydroxy-1, 4-pregnadiene-3,20-dione (16 α -hydroxy

prednisolone). He obtained 16α , 21-diacetoxy- 16β , 17α -dihydroxy-1, 4-pregnadiene-3, 20-dione upon acetylation. In addition to the melting point (161-163° C) and infrared analysis given for that compound supra, Bernstein apparently obtained the same compound, having a melting point of 217-219° C. γ max. of 3422, 1742, 1710, 1662, 1625, 1602, 1232 and 1046 cm. -1 and optical rotation of +70°, in a run employing larger quantities of starting materials.

- End of Case -